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Remarks

The above identified application has been carefully reviewed in light of the Examiner's office action mailed on July 18, 2007, which includes a final rejection of all the claims and sets a two month period for response. Applicant submits that the amendments and remarks included herein show the present claims to be allowable or if necessary, in better form for appeal. Therefore, applicant respectfully requests that this RESPONSE UNDER RULE 116 be entered and considered on its merits.

Applicant has reviewed and corrected (as indicated below) the specification as requested by the Examiner. Therefore, applicant respectfully requests the Examiner to withdraw the objection.

The first paragraph on page 16 of the specification has been amended to correct a typographical error. Specifically, the reference numeral "226" has been deleted and replaced by --126--. This amendment is fully supported by the present specification, as filed, for example, the context of the first full paragraph of page 16 and Fig. 7.

Without conceding the correctness of any of the Examiner's rejections, applicant has amended the present claims to facilitate the prosecution and allowance of the above-identified application. Applicant expressly reserves the right to seek patent protection for the original claims and for any other

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claims that are supported by the present specification in one or more later-filed related applications.

Specifically, claims 39, 60 and 66 have been cancelled, without prejudice.

In view of the above, applicant respectfully requests the Examiner to withdraw the rejections of claims 39, 60 and 66 under 35 U.S.C. 112, first paragraph, and 35 U.S.C. 103(a) as being moot.

Claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 have been rejected under 35 U.S.C. 103(a) as being unpatentable (1) over the Presentation of Kobayashi Healthcare, Inc. (Kobayashi), in view of any of JP 2002119529 (JP '529) or U.S. Patent No. 6,224,899 (U.S. '899); and (2) over JP '529 or U.S. '899 each in view of U.S. Patent NO. 5,730,957 (U.S. '957). Applicant vigorously traverses these rejections.

The present invention is directed to methods of treating hot flashes associated with menopause in a woman.

Independent claim 33 defines embodiments of the invention which comprise providing at least one cooling device in a package and instructing a woman to remove the at least one cooling device from the package and to place the cooling device at a location on the upper back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes.

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Independent claim 55 defines embodiments of the invention which comprise placing at least one cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, the cooling device comprising a water-containing gel.

Independent claim 61 defines embodiments of the invention which comprise removing at least one cooling device from a package, and placing the at least one cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes.

A hot flash associated with menopause is often experienced by a woman as a wave-like warming sensation usually radiating from the front of the chest to the head and sometimes into the hands. This wave-like warming sensation can be highly unpleasant, even embarrassing due to a flushing of the face, and can last up to five minutes. Applicant, and applicant alone, has discovered that, by placing a cooling device specifically at a location on an upper back of a woman experiencing a hot flash or prone to experiencing hot flashes, the hot flash can be successfully treated, for example, the wave-like warming sensation and the flushing of the face are significantly lessened in intensity or even eliminated.

Further, and importantly the claimed methods allow a woman to easily and discreetly treat menopausal hot flashes at virtually any time and/or place. For example, application of

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the least one cooling device at a location on an upper back is very effective in reducing or eliminating the hot flash symptoms, and, in addition, because the upper back is a discreet location of the body, advantageously facilitates privacy in that the at least one cooling device can be discreetly concealed under clothing. Thus, the present methods very effectively treat menopausal hot flashes, and do so discretely, without embarrassing the woman. This combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner while respecting the woman's privacy, achieved in accordance with the present invention, gives the woman more comfort and more confidence during an especially difficult time in her life.

Kobayashi does not disclose, teach or suggest the present invention. For example, Kobayashi does not disclose, teach, or even suggest a method of treating hot flashes associated with menopause in a woman comprising providing at least one cooling device in a package and instructing a woman to remove the at least one cooling device from the package and to place the at least one cooling device at a location on the upper back of the woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 33.

Similarly, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises placing at least one cooling device, comprising a water-containing gel, at

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a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 55.

In addition, Kobayashi does not disclose, teach or even suggest a method of treating hot flashes associated with menopause in a woman in which the method comprises the steps of removing at least one cooling device from a package, and placing the at least one cooling device at a location on an upper back of a woman who is experiencing a hot flash or is prone to experiencing hot flashes, as recited in claim 61.

As recognized by the Examiner, Kobayashi does not disclose, teach or even suggest instructing a user to place the cooling device on any specific site, let alone at a location on the upper back of the woman, as recited in the present claims. Kobayashi provides no motivation, nor any other reasonable, proper basis, for making obvious the present invention. Only after knowing of applicant's disclosure and invention would one of ordinary skill in the art even consider the present methods, including, for example, the step of instructing a woman to place a cooling device at a location on an upper back (claim 33), or placing a cooling device at a location on an upper back (claims 55 and 61). Thus, applicant submits that the rejections based on Kobayashi are derived from an improper hindsight view of applicant's own disclosure and invention.

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JP '529 does not disclose, teach or suggest the present invention. For example, JP '529 does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes including instructing the woman to place a cooling device at a location on her upper back (claim 33) or placing a cooling device at a location on the upper back of the woman (claims 55 and 61), as recited in the present claims.

U.S. '899 does not disclose, teach or suggest the present invention. For example, U.S. '899, like JP '529, does not disclose, teach or even suggest any methods for treating hot flashes associated with menopause in a woman, let alone methods of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

U.S. '957 does not disclose, teach or suggest the present invention. For example, U.S. '957 does not disclose, teach or even suggest methods for treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes ~~comprising~~ instructing the woman to place a cooling device at a location on her upper back or

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placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In stating the present prior art rejections, the Examiner never even mentions instructing a woman to place a cooling device at a location on an upper back of a woman, or placing a cooling device at a location on the upper back of the woman, experiencing a hot flash or prone to experiencing hot flashes, as recited in all of the present claims. This is so because none of the prior art even suggest instructing a woman to place at a location on an upper back or placing a cooling device at a location on the upper back of the woman, experiencing a hot flash or prone to experiencing hot flashes. This is an important limitation in all of the present claims, and is not disclosed, is not taught and is not even suggested by any of the prior art.

The Examiner seeks to remedy this clear deficiency of the prior art by ignoring it. The Examiner states that it is expected that the patch will be applied to the site of origin of hot flashes as disclosed by applicant on page 9, lines 1-5 of the present specification. Applicant vigorously objects.

First, the present claims do not recite the site of origin of hot flashes.

In addition, the Examiner is blatantly relying on applicant's own disclosure to reject applicant's own claims.

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Such blatant reliance on applicant's own disclosure is clearly an improper hindsight basis for rejecting the present claims.

Next, the Examiner, apparently in an attempt to locate some reference to the "upper back of the woman", provides a pamphlet on a "BeKool soft gel sheet product", which the Examiner apparently located on March 19, 2007.

This "BeKool" pamphlet is not prior art against the present claims, and the Examiner does not claim that the "BeKool pamphlet" is such prior art.

In view of the above, it is not clear what proper purpose this non-prior art "BeKool pamphlet" has in the above-identified application. Surely, the Examiner cannot properly rely on the non-prior art "BeKool pamphlet" as the basis for holding the present claims unpatentable.

In addition, the Examiner's attention is drawn to the fact that the above-identified application has been made special because of infringement activities. Thus, it is not surprising that the non-prior art "BeKool pamphlet" exists and is directed to embodiments of the present invention.

In any event, the non-prior art "BeKool pamphlet" cannot properly be used to render the present claims unpatentable.

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In summary, the Examiner takes the position, with emphasis, that the package and instruction recited in the present claims do not individually impart patentability, while completely ignoring an important limitation in all the present claims of instructing a woman to place a cooling device at a location on the upper back of the woman or placing a cooling device at a location on the upper back of the woman.

Moreover, as set forth in MPEP § 2143, to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaack*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Simply put, in the present situation the prior art does not disclose, teach or even suggest all of the limitations in the present claims, for example, does not disclose, teach or even suggest the "at a location on the upper back" limitation of the present claims. This fact is made all the more clear by the Examiner's explanation of the rejections which does not even

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mention the "at a location on the upper back" limitation, by the Examiner's improper reliance on applicant's own disclosure, and by the Examiner's improper citing of the non-prior art "BeKool pamphlet". Moreover, none of the prior art, taken singly or in combination, disclose, teach or even suggest the combination of advantages, that is effective and successful treatment of menopausal hot flashes in a discreet manner while respecting the woman's privacy, achieved by applicant in accordance with the present claims.

In view of the above, and contrary to the Examiner's contention, applicant submits that no prima facie obviousness case has been made out by the Examiner, and that no prima facie obviousness case exists with regard to the present claims.

Treatment of a localized lesion, bruise or sprain by applying a cooling patch to the site of the lesion, bruise or sprain, as disclosed in JP '529, is not in the least suggestive of treating a woman experiencing a menopausal hot flash or prone to experiencing such hot flashes by instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on her upper back, as recited in the present claims.

Neither Kobayashi nor JP '529, alone or in combination, discloses, teaches or even suggests a method of treating hot flashes associated with menopause in a woman experiencing a hot flash or prone to experiencing such hot flashes comprising

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instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65 are unobvious from and patentable over Kobayashi in view of JP '529, under 35 U.S.C. 103.

Further, U.S. '899 does not supply the substantial deficiencies apparent in Kobayashi with regard to the present claims.

As discussed hereinabove with regard to JP '529, applying a cooling device to a specific site, as taught in U.S. '899, in order to treat the specific site is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman experiencing a hot flash or prone to experiencing such hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman.

Further, U.S. '899's treatment of feverish subjects, which involves placing a cooling composition on a forehead of a person who is feverish, is not even remotely suggestive of methods of treating hot flashes associated with menopause in a woman comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a

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location on the upper back of the woman, as recited in the present claims.

Neither Kobayashi nor U.S. '899, alone or in combination, discloses, teaches or even suggests a method of treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman, as recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65, are unobvious from and patentable over Kobayashi in view of U.S. '899 under 35 U.S.C. 103.

The Examiner cites U.S. '957, which suggests a cool spray can be used to treat a wide variety of conditions including sunstroke, sunburn, fever, muscle fatigue and hot flashes, as teaching that "the art has recognized using cooling techniques to treat fever, hot flashes and muscle strain equally...in terms of treating them using the same cooling methods and devices."

Applicant submits that even if the art has recognized using cooling techniques to treat a wide variety of conditions, including hot flashes, the art has not recognized or even suggested treating hot flashes associated with menopause in a woman experiencing such a hot flash or prone to experiencing hot

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flashes comprising instructing the woman to place a cooling device at a location on her upper back or placing a cooling device at a location on the upper back of the woman. Moreover, using a spray to treat hot flashes can be downright embarrassing for the menopausal woman and is certainly not as effective for an extended period of time in treating the hot flash, nor as discreet as a cooling device located on the upper back of the woman.

In view of the above, applicant submits that the present claims, and in particular claims 33, 35, 36, 38, 41, 44, 45, 55-59 and 61-65, are unobvious from and patentable over JP '529 and U.S. '899 in view of U.S. '957 under 35 U.S.C. 103.

Applicant submits that each of the present dependent claims is separately patentable over the prior art. For example, the prior art does not disclose, teach or suggest the present apparatus and systems including the addition feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims, that is, claims 33, 35, 36, 38, 41, 44, 45, 55-59, and 61-65, are unobvious from and patentable over the prior art under 35 U.S.C. 103. Therefore, applicant respectfully requests the

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Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call applicant's attorney at the telephone number given below.

Respectfully submitted,



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